

CLAIMS

- Sub  
A1
1. A pelletized or extruded composition comprising:  
a core which comprises
    - (a) a carrier, and
    - (b) at least one aminoketone antidepressant.
  2. The composition of claim 1 wherein said core further comprises at least one binder.
  3. The composition of claim 2 wherein said binder comprises hydroxypropyl methylcellulose.
  4. The composition of claim 1 further comprising at least one polymer for controlled release delivery of said aminoketone antidepressant.
  5. The composition of claim 4 wherein said polymer is selected from the group consisting of shellac, methacrylic acid copolymers, hydroxypropyl cellulose, hydroxypropyl methylcellulose, ethylcellulose, cellulose acetate, cellulose acetate butyrate, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate trimellitate, polyvinyl acetate phthalate and mixtures thereof.
  6. The composition of claim 4 wherein said polymer is water insoluble.
  7. The composition of claim 6 wherein said water insoluble polymer comprises ethyl a methacrylic acid copolymer.
  8. The composition of claim 6 wherein said water insoluble polymer comprises ethylcellulose.

10071257.020802

9. The composition of claim 4 wherein said polymer is insoluble below about pH 7.
10. The composition as of claim 4 wherein said composition has a coating comprising a polymer.
11. A pelletized or extruded dosage form comprising at least one composition of claim 1.
12. The dosage form of claim 11 wherein said composition further comprises at least one binder.
13. The dosage form of claim 12 wherein said binder is hydroxypropyl methylcellulose.
14. The dosage form of claim 11 further comprising at least one polymer for controlled release delivery.
15. The dosage form of claim 14 wherein said polymer is selected from the group consisting of shellac, methacrylic acid copolymers, hydroxypropyl cellulose, hydroxypropyl methylcellulose, ethylcellulose, cellulose acetate, cellulose acetate butyrate, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate trimellitate, polyvinyl acetate phthalate and mixtures thereof.
16. The dosage form of claim 15 wherein said polymer is water insoluble.
17. The dosage form of claim 16 wherein said water insoluble polymer comprises ethylcellulose.

2007-12-27 10:00:00

a1

18. The dosage form of claim 14 wherein said polymer is insoluble below about pH 7.
19. The dosage form of claim 14 wherein said dosage form is for once daily administration.
20. The dosage form of claim 11 wherein said dosage form is a tablet, caplet, capsule or pelletized tablet.
21. The dosage form of claim 11 comprising at least two distinct compositions of claim 1.
22. The dosage form of claim 21 wherein at least one distinct composition is for controlled release.
23. A once daily dosage form comprising 150 mg of an aminoketone antidepressant, said dosage form providing an in vivo plasma profile selected from:
- (a) Mean  $T_{max}$  of about 5 or more hours
  - (b) Mean  $C_{max}$  of less than about 90 ng/ml, and
  - (c) Mean  $AUC_{0-120h}$  of more than about 350 (ng-h)ml.
24. The once daily dosage form of Claim 23 wherein said mean  $C_{max}$  is less than about 80 ng/ml.
25. The once daily dosage form of claim 23 wherein said mean  $C_{max}$  is less than about 70 ng/ml.
26. The once daily dosage form of claim 23 wherein said mean  $C_{max}$  is less than about 60 ng/ml.

27. The once daily dosage form of claim 23 wherein said mean  $C_{max}$  is less than about 50 ng/ml.
28. The once daily dosage form of claim 23 wherein said mean  $C_{max}$  is less than about 40 ng/ml.
29. A pellet comprising:
- (a) a core comprising (1) an inert carrier; (2) bupropion, its salts or isomers, or a pharmaceutically acceptable aminoketone antidepressant agent; and (3) a binder; and
  - (b) a coating comprising a pH dependent coating agent selected from the group consisting of hydroxypropyl methylcellulose phthalate and a methacrylic acid copolymer.
30. A pellet comprising:
- (a) a core comprising (1) an inert carrier; (2) bupropion, its salts or isomers, or a pharmaceutically acceptable aminoketone antidepressant agent; and (3) a binder; and
  - (b) a coating comprising a methacrylic acid copolymer and a water insoluble polymer.
31. A dosage form of claim 11, said dosage form comprising a first pellet having a coating comprising methacrylic acid copolymer and a second pellet having a coating comprising methacrylic acid copolymer.
32. The dosage form of claim 31 wherein said methacrylic acid copolymer of said first pellet is pH independent.

- Q1
33. The dosage form of claim 31 wherein said methacrylic acid copolymer of said second pellet is pH independent.
34. A dosage form comprising 150 mg of an aminoketone antidepressant wherein the aminoketone antidepressant has a dissolution profile as measured in pH 7.5 buffer at 1 hour between about 20% and 35%, at 4 hours between about 50 and 80% and at 8 hours between about 75 and 95%.
35. A dosage form comprising 150 mg of an aminoketone antidepressant wherein the aminoketone antidepressant has a dissolution profile of the active as measured in SGF 1.5 pH of less than 25% at 8 hours, of between about 25 and 45% at 10 hours and between about 50 and 80% at 18 hours.
36. A dosage form as defined in Claim 34 wherein said aminoketone antidepressant comprises bupropion or a salt of bupropion.
37. A dosage form as defined in Claim 35 wherein said aminoketone antidepressant comprises bupropion or a salt of bupropion.

20090201-15212001